Summary of Safety & Effectiveness
510K No. K003001
Grams Silk Nonabsorbable Suture

DEC 15 2000

This summary is submitted in accordance with the Safe Medical Device Act (SMDA) of 1990 and Title 21 CFR § 807.92. This summary demonstrates the equivalence of Grams American Sutures to those of the legally marked devices listed.

A. **Applicant:**

Grams American Suture, Inc.
2225 Dakota Drive
Grafton, Wisconsin 53024 USA

B. **Contact Person:** **A. J. Dimercurio**

C. **Date Prepared:** **October 16, 2000 (Original Submission 9/15/00)**

D. **Device Name:**

a. **Trade Name:** **Grams Silk Nonabsorbable Suture**
b. **Common Name: Nonabsorbable Silk Surgical Suture**
c. **Classification Name:** **Natural Nonabsorbable Silk Surgical Suture**

E. **Predicate Devices:**

- **Sofsilk Nonabsorbable Silk Surgical Suture (U. S. Surgical Corp.) 510K # K904478**
- **Silkam nonabsorbable Silk Surgical Suture (AESCULAP Inc.) 510K # K990089**
- **Silk Nonabsorbable Surgical Suture (ARC Medical Supplies 510K # K000541**
- **Lukens Silk Suture (Lukens Medical Corp.) 510K # K930942 (N80989)**

F. **Device Description:**

Grams Silk surgical suture is a nonabsorbable, sterile, surgical suture composed of an organic protein called fibroin. This protein is derived from the domesticated species Bombyx Mory (B. Mori) of the family Bombycidae. Suture characteristics include; braided wax (refined Paraffin, N.F. or Microcrystalline Wax .F.) coated, black (Hematein dyed) or white (undyed) and twisted uncoated white virgin (undyed), or twisted uncoated white (undyed).

GRAMS American Suture, Inc.™	**Summary of Safety & Effectiveness** **510K No. K003001** **Grams Silk Nonabsorbable Suture**

G. Intended Use:

"Grams Silk Nonabsorbable Suture is indicated for use in general, soft tissue approximation and/or ligation, including use in cardiovascular and ophthalmic and neurological procedures."

H. Technological Comparison to Predicated Devices:

Comparison Item	Grams American Suture Inc.	U.S. Surgical Corp.	AESCULAP Inc.	ARC Medical Supplies	Lukens Medical Corp.
Suture Material is composed of nonabsorbable flexible, braided multifilament thread of an organic protein called Fibroin. It is derived from the domesticated silkworm species *Bombyx mori,* of the family *Bombicidae.*	Same	Same	Same	Same	Same
Suture material is offered undyed and dyed with the FDA listed black colorant, Logwood extract or Hematein at concentration of 1.0% by suture weight per Title 21 CFR section 73.1410.	Same	Same	Same	Same	Same
Suture Material is supplied coated with a biocompatible coating to enhance its handling properties.	Same	Same	Same	Same	Same
Suture Material is designed being a sterile, flexible, braided multifilament thread offered in a variety of lengths and a range of diameters with or without various needles attached.	Same	Same	Same	Same	Same
The Suture Material is Intended for Use in general soft tissue approximation and /or ligation, including use in cardiovascular, ophthalmic and neurological procedures.	Same	Same	Same	Same	Same
Suture Material meets or exceeds the performance requirements for "Nonabsorbable Surgical Suture" as defined in the Official Monograph of the United States Pharmacopeia 23 and the current edition USP 24.	Same	Same	Same	Same	Same

Comparison to Predicated Device Continued:

Comparison Item	Grams American Suture Inc.	U.S. Surgical Corp.	AESCULAP Inc.	ARC Medical Supplies	Lukens Medical Corp.
Grams Suture Material meets or exceeds the performance requirements defined in the United States Pharmacopeia 23 and the current edition USP 24 for "Diameter" < 861 >	Same	Same	Same	Same	Same
Grams Suture Material meets or exceeds the performance requirements defined in the United States Pharmacopeia 23 and the current edition USP 24 for "Tensile Strength" < 881 >	Same	Same	Same	Same	Same
Grams Suture Material meets or exceeds the performance requirements defined in the United States Pharmacopeia 23 and the current edition USP 24 for "Needle Attachment" < 871 >	Same	Same	Same	Same	Same
Grams Suture Material meets or exceeds the performance requirements defined in the United States Pharmacopeia 23 and the current edition USP 24 for "Suture Length Requirement"	Same	Same	Same	Same	Same
Grams Suture Material is packaged in a same or equivalent manner with sterile single or double package having labeling conforming to 21 CFR and USP XXIV.	Same	Same	Same	Same	Same

I. Conclusion:

Grams American Silk Suture is composed of the same material, as are the predicated devices and the same design being a sterile, flexible, braided multifilament threads meeting all the requirements of the United States Pharmacopeia. The Grams American Silk Suture is manufactured in the same manner as the predicate devices, being produced from de-gummed and bleached yarn of natural silk harvested through sericulture of B. mori and braided in operations considered standard in the fiber industry to form the finished suture fiber. The manufacturer supplies to Grams American Suture the same suture materials as it supplies to other suture manufacturers including some (if not all) those listed above. Grams American Suture believes the information demonstrates substantial equivalence to the above legally marketed devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2000

Mr. Anthony J. Dimercurio
Vice President of Operations
Grams American Suture, Inc.
2225 Dakota Drive
Grafton, Wisconsin 53024

Re: K003001
Trade Name: Natural Nonabsorbable Silk Surgical Suture
Regulatory Class: II
Product Code: GAP
Dated: September 15, 2000
Received: September 26, 2000

Dear Mr. Dimercurio:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

GRAMS
American Suture, Inc.™

Intended Use Statement

K003001

"510(k) Notification"

21CFR 878.5030 Natural Nonabsorbable Silk Surgical Suture

"Grams Silk Nonabsorbable Suture is indicated for use in general, soft tissue approximation and/or ligation, including use in cardiovascular and ophthalmic and neurological procedures."

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003001